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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,879	08/12/2002	Pieter Cornelis Langeveld	246152016800	1306

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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/089,879	**Applicant(s)** LANGEVELD ET AL.	
	Examiner Robert A. Zeman	**Art Unit** 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 October 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-6,12 and 13*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

ADVISORY ACTION

Applicant's arguments are predicated in part on amendments not made of record. Consequently, any rejection not explicitly addressed below is maintained for the reasons set forth in the previous Office action.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-6 and 12-13 under 35 U.S.C. 102(b) based upon a public use or sale of the invention is maintained for reasons of record.

Applicant argues:

1. The Premi®Test egg protocol was disclosed after the filing date of the present application as exemplified by the attached leaflet.

2. The claimed process is not directed to the Premi®Test itself but rather testing an egg sample for antimicrobial residue using Premi®Test.

3. There is no evidence of record that the "public use or sale of the invention" occurred in the United States.

Applicant's arguments have been fully considered and deemed non-persuasive.

The insert provided by Applicant is to a product named Premi®Test-egg which is a different product than that depicted in Exhibit B of Applicant's response filed on 10-7-2005. Said exhibit disclosed the use of the Premi®Test product with egg samples. The basis of the rejection is the date the Premi®Test was publicly disclosed and when the insert exemplified by Exhibit B was made publicly available. The Geijp reference was cited as evidence of the public availability of the Premi®Test. Exhibit B demonstrates that the Premi®Test constitutes the instant invention.

With regard to Point 3, the issue of public use or on sale activity has been raised in this application. In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as follows: the date the Premi®Test became publicly available and the date the insert (exemplified by Exhibit B) was originally released. It should be noted that the dates that Applicant is relying on as the "availability dates" of the Premi®Test-egg and the Premi®Test are merely the dates the particular insert was printed and do not necessarily represent the earliest availability date.

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

As outlined previously, the method that constitutes the instant invention is disclosed in the instruction sheet for the Premi®Test sample procedure for eggs (Exhibit B of Applicant's response filed on 10-7-2005). The procedure set forth in said instruction sheet anticipates all the limitations of the instant claims. Moreover, it is apparent the Premi®Test was publicly disclosed prior to the priority date of the instant application as evidenced by Geijp et al. (Abstract book

"Third International Symposium of Hormone and Veterinary Drug Residue Analysis, Brugge",1998).

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-6 and 12-13 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues:

1. The claimed process specifically avoids the interpretation that the inactivating step would encompass the antimicrobial residues to be detected by reciting the limitation "without inactivating the microbial residue to be detected".

Applicant's arguments have bee fully considered and deemed non-persuasive.

The instant claims recite "**any** compound naturally present in the sample that is capable of inhibiting growth of the test organism". Moreover, while the claims recite the limitation "without inactivating the microbial residue to be detected", the specification is silent with regard to how this is accomplished given that the "naturally present compounds" and the residue to be

detected are all unknowns. Consequently, the specification is not enabling for the method as claimed.

As outlined previously, the method steps set forth in the rejected claims seem to render said method inoperative. Applicant's argument that the claim amendment is sufficient to overcome the rejection is deemed non-persuasive. Step (ii) of claim 1 still requires that the test sample and the test composition to be heated until any compound that inhibits microbial growth in the sample is inactivated. This would encompass not only the antimicrobial substances that lead to false positives but also the antimicrobial residues that are to be detected. Consequently, one would not be able to get a positive result (i.e. detect an antimicrobial residue) utilizing the recited method steps.

The new matter rejection of claim 1 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons of record.

Applicant argues:

1. The limitation is supported by the bridge of pages 1-2 of the specification as well as page 3, lines 22-25.

Applicant's arguments have been fully considered and deemed non-persuasive.

The cited portions of the specification are drawn to lysozymes. Moreover, neither passage recites the limitation "absent said inactivating step".

As outlined previously, Applicant has amended claim 1 to recite, "any compound naturally present in the sample that is capable of inhibiting growth of the test microorganism leading to a false positive results absent said inactivating step...". This phrase does not appear in the specification, or original claims as filed. The portion of the specification cite by Applicant for the basis for this limitation in the application does not support said limitation. Therefore this limitation is new matter.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert Navarro can be reached on (571) 272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ROBERT A. ZEMAN
PRIMARY EXAMINER
November 1, 2006